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ASAP LAB

DIAGNOSTICS
Molecular

Proposal

Department of Defense

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Introduction

We are pleased to present you our proposal to provide diagnostic testing. ASAP Lab is a small specialized diagnostic laboratory that currently services customers throughout the United States. As you will find mentioned throughout this response, ASAP Lab is dedicated to the highest customer service we can provide.

We strive to provide the highest quality diagnostic services in the industry, centered around high customer care. We provide fast, accurate measurable results to allow you to make informed decisions for your patients. We have designed our services around your needs to provide quick, actionable results. With a vast array of services available we can assist with identification of pathogens for treatment.

In the past, when only traditional cultures were available to detect infection-causing fungi and bacteria, doctors had to wait for days and sometimes weeks before they could begin treating infections. With the advent of molecular diagnostics, however, this is no longer the case.

Molecular diagnostic tests allow physicians to identify, with impressive specificity and accuracy, the pathogens causing infections in their patients. This allows you to devise the most appropriate and personalized treatment plans- improving treatment outcomes and the overall quality of care provided.

There are many advantages to utilizing molecular diagnostic methods in place of cultures. For one, when compared to the many days/weeks it takes to obtain results with cultures, molecular testing is much faster. Its results are available within 24-48 hours. This means diagnoses can be made without delay and treatment for infections can commence before the infection spreads.

In a recent study, we found that PCR can detect more bacteria than traditional cultures, and can detect bacteria that cultures miss. 582 patients sent Urine samples. PCR detected 22 out of 24 (92%) organisms whereas a culture analysis only detected 15 (62%).

We are excited about our testing as a form of antibiotic resistance. Antibiotic resistance, which most commonly occurs due to misuse and overuse of certain antibiotics that then cause bacteria to alter as a response to the medication is becoming a major public health and safety issue. In fact, according to the Centers for Disease Control and Prevention (CDC) more than two million people are ill every year with an antibiotic-resistant infection, and from those ill an estimated 23,000 die as a result.

We are backed by Private Equity and we're working on developing new technology solutions to patients based on lab test results. We are investing heavily in our technology to be able to provide the highest service to our customers.

We are ready and willing to serve you.

Respectfully,



Tim Buckman
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Our Commitment to the Department of Defense

We are willing to go above and beyond for You

Rapid Turn Around Time

- Results delivered in 24-48 hours for most tests. Some more complicated tests require additional time but our goal is always to have results ASAP for better patient outcomes.

Dedicated Account Manager

- Will be available for your every need. You will have your own customer service representative that you can speak with whenever you need.

Custom Solutions to Problems

- We're a nimble solution and as a Priority Account, we will be able to build our offering around your requests.
- Need something different? Just ask and we'll do whatever we can to make it work

Validate additional pathogens if desired

- We're getting new equipment, with a commitment from the Department of Defense we can add pathogens you'd like to test for if we don't already – specifically designed around you

Direct Access to the Scientific Staff

- If you have questions about the science behind the tests we will schedule meetings with our scientific staff

Mobile lab testing

- As required we have the ability to add a mobile lab that offers field collection and same day service

Detailed Sample Tracking (In Process)

- SpectraPath is a comprehensive web-based technology platform specifically designed to help effectively manage all specimen management needs
- As a new feature, SpectraPath now offers an optional RFID solution that integrates intelligence asset tracking and temperature monitoring

Technology

- We're investing in new ways to identify patient ailments sooner. If there are specific ideas that you would like to explore, we'll adjust, and the Department of Defense will be the first to benefit from advanced patient testing.

About Us

ASAP Lab has a niche focus on diagnostics. ASAP currently conducts testing of samples from individual physicians, hospitals and facilities. Diagnostic testing through ASAP Lab is convenient and reliable. Our testing and quality assurance programs exceed industry guidelines and expectations. Combined, our highly trained lab experts and state-of-the-art technologies, in conjunction with our compliance policies, serve to demonstrate our commitment to accurate results. Our key principles enable us to appropriately aid physicians and their clients with a comprehensive approach to clinical diagnostic services.

We are a team of professionals specializing in diagnostic testing. ASAP Lab is a preferred choice for being **TIMELY, EFFICIENT & ACCURATE**.

Why Choose Us?

ASAP is committed to remaining on the cutting edge of diagnostic medicine, continually advancing our testing capabilities by introducing the most advanced and comprehensive techniques, for the benefit of the clinicians who use our services and the patients who rely on us both for accurate diagnoses and the most effective treatments.

- ☑ Expedited Patient Results
- ☑ Unparalleled Specificity and Precision Results
- ☑ Analysis Provided by an Expert Team of Laboratory Specialists
- ☑ Cutting-edge Technologies and Methodologies, Backed by Ongoing Research
- ☑ Dedicated, Responsive Customer Service
- ☑ Convenience for your patient
- ☑ Fully supportive plan for anti-biotic stewardship

Experience

ASAP Lab was formed in 2013 to provide lab services. We perform thousands of test results annually. As a small nimble company, we can quickly customize our services for your particular needs.

A few interesting facts about ASAP

- **60%** of our owners are either active or retired in the US Military
- We are classified as a small business
- We host webinars and bring in leading consultants to help find better solutions for better patient outcomes.

As a high-complexity CLIA accredited laboratory, we assist clinicians and health care providers to quickly identify the pathogens and underlying causes of disease. We know better patient outcomes are achieved through fast, accurate, and reliable laboratory results.

Customer Service

As you will see throughout this proposal, we believe in offering the highest customer service we can. As an important account of ours, you would have direct access to your specific Account Manager as well as our Director of Operations and CEO as needed. The Department of Defense will be a high Priority Account and we will do everything we can to accommodate you.

For any problem you should have, you will have a direct point of contact. Your contact will find the appropriate resolution for any issue you may have, and will have the authority to make any changes necessary.

You may contact us at any time for any problems, including but not limited to:

- Testing & Results
- Lab Confirmations
- Shipment problems, questions, or delays
- Ordering problems, questions or delays
- Billing problems or questions
- Any other problems related to the accounts or questions about our services.

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Problems will be resolved ASAP.

Implementation Timeline

The implementation will be a seamless process. Upon a selected start date we would ship the materials needed to start. We can have you up and running within a week.

Our entire team will make sure implementation goes without a hitch.

Our Testing Services

Molecular Diagnostics (PCR) – Infectious Disease

In the past, when only traditional cultures were available to detect infection-causing fungi and bacteria, doctors had to wait for days and sometimes weeks before they could begin treating infections.

With the advent of molecular diagnostics, however, this is no longer the case.

ASAP Lab’s tests provide doctors with information about the nature of the pathogen(s) causing the infection(s) being dealt with.

PCR can detect more bacteria than traditional cultures, and can detect bacteria that cultures miss. 582 patients sent Urine samples. PCR detected 22 out of 24 (92%) organisms whereas a culture analysis only detected 15 (62%).

Testing with high sensitivity and specificity compared to the traditional urine culture technique. We identify pathogens difficult to grow in culture and use a large pathogen menu.

Culture VS PCR molecular technique for UTIs and other urinary tract conditions

1. **Turnaround time:** Urine cultures are slow. It usually takes about 2 to 3 days to obtain urine culture and antimicrobial sensitivity results. Still more, the analysis of certain types of bacteria that grow slowly will sometimes take even longer. However, with molecular testing techniques like PCR, turnaround time is much faster. You can expect to obtain results within **24 to 48 hours**.
2. **Detection of bacteria:** Urine cultures do not detect many bacteria that cause UTIs and other urinary tract conditions. Investigators at the 2018 annual meeting of the Large Urology Group Practice Association reported that a PCR test “identifies more bacteria than traditional urine culture in patients with symptomatic urinary tract infection (UTI).” PCR was able to detect 22 out of the 24 targeted organisms while traditional culture was able to detect only 15. The investigators also noted that most of the organisms' cultures were not able to detect fastidious bacteria (those that are slow-growing or require additional conditions to grow).
3. **Contribution to antibiotic resistance:** Antibiotic resistance is a public health threat— one which many bodies and initiatives are actively combating. Urine cultures contribute to antibiotic resistance because its slow turnaround time and limited sensitivity encourages the empirical prescription of antibiotics to patients with UTIs. Fortunately, with PCR tests, results are available quickly—preventing the need for initial empirical treatment of UTIs. Additionally, molecular tests like PCR identify resistance markers, allowing urologists to avoid the prescription of ineffective antibiotics to patients.

Sample URO Panel for STI / UTI

Urine STI Panel

- Mycoplasma hominis
- Ureaplasma urealyticum
- Mycoplasma genitalium
- **Leukorrhea Panel**
 - Trichomonas Vaginalis
 - Neisseria gonorrhoeae
 - Chlamydia trachomatis

UTI ID Panel

- E. Coli
- Staphylococcus aureus
- Staphylococcus Saprophyticus
- Enterococcus faecalis
- Ureaplasma urealyticum
- Mycoplasma hominis
- Candida Species
- Proteus Mirabilis
- Klebsiella Pneumoniae
- Morganella morganii
- Serratia Marcescens
- Klebsiella oxytoca
- Enterobacter cloacae
- Providencia Stuartii
- Pseudomonas Aeruginosa
- Streptococcus Agalactiae
- “Resistance Markers”
- “Antibiotic Sensitivity”

Antibiotic resistance, which most commonly occurs due to misuse and overuse of certain antibiotics that then cause bacteria to alter as a response to the medication is becoming a major public health and safety issue. In fact, according to the Centers for Disease Control and Prevention (CDC) more than two million people are ill every year with an antibiotic-resistant infection, and from those ill an estimated [23,000 die as a result](#).

Using the Polymerase Chain Reaction (PCR) molecular technique, ASAP Lab provides a comprehensive panel for different types of physicians.

- ❖ Urologists (UTI / STI)
- ❖ Podiatrists and Wound Care Specialists
- ❖ Nail Infections
- ❖ Gastroenterology
- ❖ Women's Health
- ❖ Respiratory (Ear/Nose/Throat Infections)



	ASAP LAB	Others
Method	PCR	Culture
Sensitivity	98%	2%
Yeast Identification	YES	Rarely
Evidence-based therapeutic options	YES	NO
Isolate antibiotic-resistant genes	YES	MAYBE
Anaerobic identification	YES	NO
Pathogens tested per sample	15-20	1
Turn Around Time	24-48 Hours	5+ Days

Toxicology

As many physicians know, prescribing a patient an antibiotic or other medication to treat their symptoms and condition is only part of the equation when it comes to treatment. The other half relies on the patient's willingness to take and follow prescriptions as directed. Research has shown this piece of the puzzle is much trickier to manage, as [an estimated 125,000 deaths per year in the U.S. are due to medication non-adherence](#), according to a study published in the *American Heart Journal*. That same study also found that out of the 3.2 billion medications that are prescribed in the U.S. each year, only half of those are taken as directed.

More than 130 people die everyday from opioid overdoses. In a significant number of these deaths, prescription opioids are used. The National Institute of Drug Abuse (NIDA) also estimates that about 21-29% percent of patients misuse opioids prescribed for chronic pain, and roughly 8-12% end up developing an opioid use disorder. These are distressing figures that the government, medical community and the public are seeking ways to reduce.

Aside from the patient's condition not improving or worsening, this non-adherence is costing both insurance companies and the patient more money. The National Council on Patient Information and Education reported that [not taking prescriptions as directed costs the U.S. health care system \\$100 billion annually, which includes \\$47 billion for drug-related hospitalizations](#). Failure to take prescription medication at all can cost the patient up to \$2,000 per year in additional doctor's visits and extra treatment or medication needed as a result. Prescription neglect is also a big part of why employer's keep increasing insurance costs for covered employees, making them pay a larger percentage through co-insurance and deductibles.

Physicians, in particular, have an important role to play in the prevention of opioid use disorders and overdoses in patients. The NIDA observes that by virtue of the fact that over 84% of Americans come in contact with healthcare professionals yearly*, physicians are well placed to detect non-medical use of prescription drugs. Consequently, they are advantageously positioned to prevent the development of substance use disorders.

To aid physicians, the Center For Disease Control (CDC) published the CDC Guideline for Prescribing Opioids for Chronic Pain. The guideline asserts that physicians can reduce the risks of long-term opioid pain (like opioid use disorder and overdose) by implementing the following recommendations:

- Opioids should only be used when their benefits for pain and function seem to outweigh the risks the patient faces. When prescribed, opioids should be used along with non-pharmacologic methods of pain management as well as other non-opioid medication.
- Treatment goals should be established with the patient, and arrangements should be made to discontinue the use of opioids if their risks start to outweigh the benefits.
- The lowest effective dose of immediate-release opioids should first be prescribed for acute pain.
- Data from state prescription drug monitoring programs should be used to periodically review a patient's history of prescription medication. This will help the physician discern if the patient is on opioid dosages or drug combinations that could significantly increase the risk of substance use disorders and/or overdose.
- Urine drug tests to check for prescribed opioids and other illicit substances should be carried out before going ahead to prescribe opioids. The tests should also be carried out at intervals- at least annually.

The guideline also sets out some clinical reminders:

- Opioids should not be the first choice for treating chronic pain.
- Discussions with the patient about the risks, benefits, and availability of other therapies besides from opioids should take place.
- Opioids for acute pain should be prescribed only to the extent to which they are needed.

Utilizing ASAP Lab's Toxicology services to monitor opioid use

ASAP Lab offers urine drug tests to assist physicians in preventing opioid use disorders and overdose. Employing the enzyme immunoassay technique, ASAP Lab's urine screening test can give information about the levels of prescription opioids in a patient's system. Illegal drugs like heroin, which is commonly used in combination with prescription opioids, can also be detected. Other commonly abused drugs that can be checked for are oxycodone, amphetamine, ecstasy, methadone, benzodiazepines and phencyclidine.

Specimen Validity

Synthetic urine is fast becoming one of the most common tools used to cheat drug tests. It is readily available can mimic real urine in many ways, including content, density, color, odor and PH balance- making it very hard to detect. The US military, for instance, has difficulty detecting it because the samples they test do not usually undergo specimen validity testing (SVT). However, even in civilian situations where SVT is required, studies show that it is still not always possible to differentiate between synthetic and real urine.

For doctors, the situation is even more dire. There are many instances where being able to differentiate between real and synthetic urine can be crucial in providing quality healthcare and preventing patient deaths.

Some of them include:

- **Opioid prescription and monitoring:** According to the Guideline for Prescribing Opioids for Chronic Pain published by the Centers for Disease Control and Prevention (CDC), you should

perform drug tests before prescribing opioids to patients. After, prescription, you should also go further to order routine drug tests to check the patient's opioid levels. These steps can potentially prevent patients from developing substance use disorders or overdosing on opioids.

- **Prescription of other controlled drugs:** Just like with opioids, urine drug tests are crucial to the prescription and monitoring of other controlled prescription drugs.
- **Medication adherence:** Conducting routine urinalysis for patients is one of the standard methods of keeping an eye on medication adherence. Patients subverting your ability to test their real urine can seriously affect healthcare outcomes, especially with chronic conditions.

ASAP Lab's synthetic urine detection method

ASAP Lab gives you the ability to verify the integrity of the specimen your patients provide. ASAP Labs can detect synthetic urine with a custom 5 test panel. Most labs' specimen validity testing only measure pH, creatinine and specific gravity. ASAP Lab is one of the few labs where two additional tests-- oxidant history test and counterfeit urine test- are carried out on the specimen. The panel's 5 tests can identify 8 different classes of subversion in urine samples.

Pharmacogenetics

Drug-gene testing is also called pharmacogenomics, or pharmacogenetics. All terms characterize the study of how your genes affect your body's response to medications. The word "pharmacogenomics" is combined from the words pharmacology (the study of the uses and effects of medications) and genomics (the study of genes and their functions).

Your body has thousands of genes that you inherited from your parents. Genes determine which characteristics you have, such as eye color and blood type. Some genes are responsible for how your body processes medications. Pharmacogenomic tests look for changes or variants in these genes that may determine whether a medication could be an effective treatment for you or whether you could have side effects to a specific medication.

- Of more than 4 billion prescriptions issued each year, about half do not work as intended. Adverse drug reactions (ADRs) account for up to 7% of all hospital admissions and up to 20% of re-admissions, according to estimates
- ADRs are the fourth leading cause of death and are estimated to cost \$136 billion annually
- Poor compliance accounts for 33% to 69% of ADRs that result in hospital admissions.
- ASAP Lab PGx Test eliminates the risk of Adverse Drug Reactions for your practice
- Tool to help doctor prescribe the right drug, the right dose, the right indication, to the right patient at the right time
- Saves Lives – over 106,000 deaths annually in the U.S. (4th leading cause of death)
- Saves Money - \$136 billion annually spent on hospitalization and medical costs reported by the FDA due to ADR's. Current malpractice cost payout leader. The Pharma companies use cytochrome typing on labels to transfer liability from them to the doctors. There is no way to transfer liability back to the pharma companies without PGX testing. There are thousands of ADR lawsuits in Florida now directed at the prescribing physician. Before, these were primarily directed at the pharma companies. In Florida, approximately 70% of all malpractice lawsuits are based on drug-prescribing liabilities.
- Saves Time – doctors will have better use of time (one of their most valuable and sparing assets) and avoids trial and error to determine the right medication for the right patient
- Versatile – covers 200 of the most commonly prescribed medications and is an invaluable addition to any patient's medical record

- FDA recommended – 50% of the population takes 2 or more medications. Only 25% are effective
- Improved quality of care for the practice and the patient

Cardiovascular

Comprehensive Cardiovascular Panel covers a broad spectrum of inherited heart conditions and diseases. Medical conditions that run in a family are inherited or genetic—caused by changes in genes that are passed from generation to generation. Many different types of heart disease can be inherited.

Genetic testing for inherited heart disease can identify the cause of a family's heart disease. Testing can also help determine which specific relatives are at risk for developing it, beyond the general assumption that 50% of the family will develop the condition.

Parkinson's, Alzheimer's and Dementia Panels

The Parkinson Disease Comprehensive Panel examines 26 genes associated with an increased risk of developing the neurodegenerative condition: Parkinson Disease.

Patients with a personal and/or family history of Parkinson's disease. Parkinson Disease is characterized by progressive movement and balance issues. The progression of symptoms is often a bit different from one person to another due to the diversity of the disease. Warning signs include, but are not limited to involuntary shaking of the hands, legs, jaw or tongue (tremors), slow movement (bradykinesia), stiff limbs (rigidity), or gait (walking) and balance problems.

Patients identified with a disease-causing change (a pathogenic or likely pathogenic variant) in a gene on this panel have an increased risk of developing the associated neurodegenerative disease. Genetic testing may be beneficial in the planning and decision-making process for treatment, psychosocial counseling, research study enrollment, and support programs for caregivers and patients. Your patient's family members can also be tested to help define their risk. If a pathogenic variant is identified in your patient, close relatives (children, siblings, and parents) are up to 50% more likely to also be at increased risk.

Beacon Carrier Screening

Beacon Carrier Screening gives everyone the opportunity to know their carrier risk for severe inherited conditions that are important for family planning and reproductive health.

The Beacon ACOG/ACMG panel screens for the most common genetic disorders seen within the general population. Carrier screening for these disorders have been recommended by the American College of Obstetricians and Gynecologists (ACOG) and the American College of Medical Genetics and Genomics (ACMG) for all pregnant women and women considering pregnancy.

Hereditary Cancer

The mapping of the human genome has provided medical professionals with the ability to refine a patient's cancer risk through the analysis of inherited mutations.

Genetic tests screen a number of known genes related to hereditary cancers. The goal of every test is to determine a patient's risk of cancer. This knowledge can help your physician to develop the appropriate or preventative treatment plan for early detection. If the results of your test indicate an increased risk for cancer, you can order tests like mammograms, colonoscopy and CT scans for any possible diagnosis and immediate intervention.

Routine Blood Chemistry

ASAP Lab can meet all of your blood analysis needs through our broad array of testing under the following classifications:

- Hematology
- Microbiology
- Endocrinology
- Blood Chemistry
- Blood Allergen
- Serology

We are able to create custom blood profiles selected by a physician as well as individualized testing options.

Some of the more common panels include:

Comp. Metabolic Panel	Total Protein	Vitamin B-12	Uric Acid
Albumin	ALT	PSA Total	Folate
BUN (Urea Nitrogen)	Alkaline Phosphate	PSA Free	Amylase
Calcium	AST	Ferritin	Lipase
Carbon Dioxide	CBC	Bilirubin, Total	
Chloride	Lipid	Bilirubin, Direct	FSH
Creatinine	Hemoglobin A1C	GGT	Prolactin
Glucose	Thyroid	Iron	Luteinizing Hormone (LH)
Potassium	TSH	TIBC	Testosterone
Sodium		Magnesium	Progesterone
Total Bilirubin	Vitamin D	Phosphorus	Estradiol

Appendix